Baxter H1N1 to Resilience

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The vaccine technology Baxter sold to Nanotherapeutics in 2014—specifically the Vero cell-based platform—was the same core technology Baxter used to develop its H1N1 pandemic vaccine, *Celvapan*.

🔬 Details on the Technology: Vero Cell Platform

- **Vero cells** are derived from kidney cells of the African green monkey and are a continuous cell line widely used for virus cultivation.
- Unlike traditional egg-based vaccine production (which takes longer and can be problematic during pandemics), **Vero cell-based technology** allows for faster and more scalable manufacturing.
- Baxter's use of this platform enabled them to develop vaccines without the use of adjuvants or preservatives, which was notable in their *Celvapan* formulation.

💉 Baxter's H1N1 Vaccine: Celvapan

- Celvapan was **Baxter's proprietary pandemic flu vaccine** developed using the Vero cell platform.
- It was approved by the **European Medicines Agency (EMA)** in **2009** for use against the H1N1 (swine flu) pandemic strain.
- Celvapan was **inactivated and non-adjuvanted**, and was produced in Baxter's facilities in Bohumil, Czech Republic – the same facility and technology later sold to Nanotherapeutics.

🤝 Sale to Nanotherapeutics

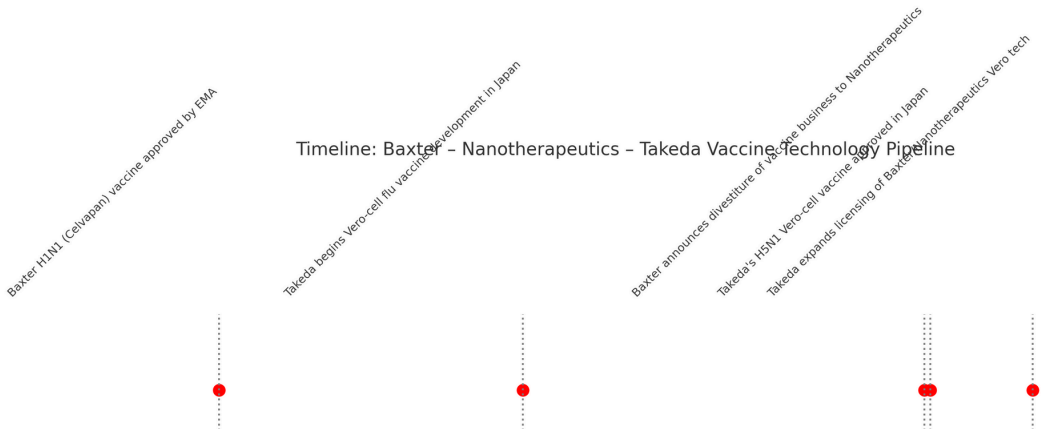
- In **December 2014**, Baxter **divested its entire vaccine production operations**—including:
  - The **Bohumil facility** in the Czech Republic,
  - All associated **intellectual property and production rights**,
  - The **Vero cell platform** used to develop and manufacture Celvapan and other pandemic/seasonal flu vaccines.

💼 Post-sale Use by Nanotherapeutics

- Nanotherapeutics used this platform primarily through partnerships (notably with **Takeda**).
- Takeda adapted the same Vero cell technology for **its own H5N1 vaccine**, which was approved in Japan by 2014.
- Nanotherapeutics' CEO confirmed this technology enhanced their portfolio—both for domestic use and for collaborations involving pandemic preparedness and government contracts (e.g., BARDA-related pro

The Vero cell-based vaccine technology acquired by Nanotherapeutics from Baxter was the same technology Baxter used to develop Celvapan, its H1N1 pandemic vaccine. The technology enabled rapid, cell-based production of influenza vaccines without the limitations of egg-based systems and was considered a strategic platform for pandemic response.

Visual timeline showing key events in the **Baxter–Nanotherapeutics–Takeda** vaccine technology pipeline, with a focus on the Vero cell platform:


Timeline: Baxter – Nanotherapeutics – Takeda Vaccine Technology Pipeline
Baxter H1N1 (Celvapan) vaccine approved by EMA
Takeda begins Vero-cell flu vaccine development in Japan
Baxter announces divestiture of vaccine business to Nanotherapeutics
Takeda's H5N1 Vero-cell vaccine approved in Japan
Takeda expands licensing of Baxter/Nanotherapeutics Vero tech

1. **2009:** Baxter's *Celvapan* (H1N1 vaccine) is approved by the EMA.
2. **2012:** Takeda initiates development of influenza vaccines using the Vero cell system in Japan.
3. **Dec 2014:** Baxter sells its Vero cell-based vaccine operations and Bohumil facility to Nanotherapeutics.
4. **Dec 2014:** Takeda's H5N1 vaccine, developed using this technology, is approved in Japan.
5. **Oct 2015:** Takeda expands its licensing agreement to include broader use of the Vero platform globally.

📄 1. Baxter's Sale of Vero Cell Vaccine Platform to Nanotherapeutics (December 2014)

- **Press Release:** On December 15, 2014, Baxter International Inc. announced the sale of its proprietary Vero cell technology and related assets, including its production facility in Bohumil, Czech Republic, to Nanotherapeutics, Inc. (investor.baxter.com)
- **Details:** The agreement encompassed all assets related to the Vero cell platform, including vaccines for H5N1, H1N1, and seasonal influenza, as well as investigational vaccine programs for Ross River virus, Chikungunya disease, and West Nile virus. (GEN)

📄 2. Takeda's Exclusive License to Baxter's Vero Cell Technology (December 2010)

- **Agreement:** In December 2010, Takeda Pharmaceutical Company Limited entered into a development, license, and technology transfer agreement with Baxter, granting Takeda exclusive rights to Baxter's Vero cell culture-based influenza vaccine technology for the Japanese market. (GEN)
- **Objective:** The collaboration aimed to develop a pandemic H5N1 vaccine for manufacture in Japan, with Takeda seeking funding from the Japanese government to construct a Vero cell-based influenza manufacturing facility. (Manufacturing Chemist)

📄 3. Takeda and Nanotherapeutics Agreement to Expand Commercialization and Technology Access Rights (August 2015)

- **Announcement:** On August 26, 2015, Takeda and Nanotherapeutics announced an agreement providing Takeda with expanded commercialization and technology access rights related to Nanotherapeutics' Vero cell technology platform. (Takeda)
- **Background:** Nanotherapeutics had acquired the Vero cell technology platform from Baxalta, formerly Baxter International's BioScience division. (Takeda)

📄 4. EMA Recommendation for Authorization of Celvapan (October 2009)

- **Regulatory Update:** On October 2, 2009, the European Medicines Agency recommended that Celvapan, Baxter's pandemic influenza vaccine (H1N1), be granted marketing authorization. (European Medicines Agency (EMA))
- **Significance:** Celvapan was the first cell culture-based and non-adjuvanted pandemic influenza vaccine to receive such a recommendation in the European Union. (News-Medical)

📄 5. Baxter Receives EC Approval for Celvapan H1N1 Pandemic Flu Vaccine (October 2009)

- **Confirmation:** On October 7, 2009, Baxter confirmed that the European Commission granted marketing authorization for Celvapan H1N1 pandemic vaccine, produced using Baxter's Vero cell technology. (News-Medical)
- **Distribution:** Following approval, Baxter began delivering the vaccine to national health authorities with existing agreements, including the UK and Ireland. (Contract Pharma)

Baxter – Nanotherapeutics – Takeda Vaccine Technology Timeline & Documentation

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Between 2008 and 2015, Baxter International, Nanotherapeutics, and Takeda Pharmaceuticals were involved in a series of technology transfers and vaccine development partnerships focused around a proprietary Vero cell-based platform. This platform was used for pandemic and seasonal influenza vaccine production, notably including Baxter's H1N1 (*Celvapan*) vaccine.

Technology Overview

- **Vero cells**: Derived from African green monkey kidney cells, used to cultivate influenza viruses without eggs.
- Used in Baxter's H1N1 vaccine *Celvapan*, approved in 2009 by the EMA.
- Platform allowed rapid, scalable vaccine production and avoided traditional egg-based manufacturing constraints.

Timeline of Key Events

- **2009**: Baxter's *Celvapan* (H1N1 vaccine) approved by the European Medicines Agency.
- **2010**: Takeda licenses the Vero cell platform from Baxter.
- **2012**: Takeda begins development of its own flu vaccine using the Vero platform.
- **March 2014**: Takeda's H5N1 Vero-cell–based vaccine approved in Japan.
- **December 2014**: Baxter sells its vaccine operations and Bohumil (Czech Republic) manufacturing plant to Nanotherapeutics.
- **August 2015**: Takeda expands rights with Nanotherapeutics for global commercialization of flu vaccines based on the Vero platform.

Key Agreements and Uses

- Baxter sold its entire Vero cell vaccine operation, including intellectual property, equipment, and manufacturing facility, to Nanotherapeutics in December 2014.
- Nanotherapeutics used the acquired platform in collaboration with industry partners, notably Takeda.
- Takeda received a $70M subsidy from the Japanese government to scale production at its Hikari plant.
- The same Vero cell platform used in Baxter's H1N1 vaccine was also applied in Takeda's H5N1 pandemic flu vaccine, which received regulatory approval.

Source Documents

1. **Baxter's Divestiture to Nanotherapeutics (Dec 2014)**
   "Baxter to Divest Vero Cell Vaccines Platform to Nanotherapeutics"
   Baxter Investor News
2. **Takeda's H5N1 Vaccine Approval (Mar 2014)**
   "Takeda Announces the New Drug Application Approval of Cell-Cultured Influenza Vaccine H5N1 TAKEDA"
   Takeda Newsroom

3. **Takeda and Nanotherapeutics Expanded Agreement (Aug 2015)**
   "Takeda and Nanotherapeutics Announce Agreement to Expand Takeda's Commercialization and Technology Access Rights in Support of Influenza and Other Vaccine Programs"
   Takeda Newsroom
4. **Japan's Subsidy for Vaccine Expansion (May 2014)**
   "Takeda Wins $70M from Japan to Bump Up H5N1 Vaccine Production"
   Fierce Pharma
5. **Baxter Licenses Technology to Takeda (Dec 2010)**
   "Baxter Licenses Vero Cell-Based Influenza Vaccine Technology to Takeda"
   News Medical

Nanotherapeutics to Ology to Resilience

National Resilience is a biotechnology company that was founded in 2020. It emerged from the combination of several biotech entities, including *Resilience* (previously known as *National Resilience, Inc.*) and *Avenir*, with backing from prominent investors. The company was formed to address the critical gaps in the biopharmaceutical manufacturing space, especially in terms of developing and scaling the production of vaccines, gene therapies, and other advanced biologics. Their goal is to improve the resilience of healthcare systems by ensuring that essential biologics can be produced more effectively and at a larger scale.

They work across a range of advanced manufacturing capabilities, aiming to accelerate the time it takes for new therapies to reach patients, especially in emergencies like pandemics.

Avenir was a biotechnology company that specialized in biomanufacturing, particularly focusing on the development of advanced technologies for producing complex biologic drugs, such as vaccines and cell and gene therapies. The company was involved in enhancing the scalability and efficiency of biologic manufacturing processes.

Avenir, alongside its partners, sought to address challenges in producing biologics at a large scale while maintaining the necessary quality and consistency. The company's focus on high-quality manufacturing and cutting-edge technologies made it an attractive partner in the broader biopharmaceutical ecosystem.

In 2020, Avenir was one of the entities that contributed to the formation of National Resilience, bringing its expertise and infrastructure to the new company's goal of reshaping the future of biologic manufacturing. By merging Avenir's capabilities with those of other companies, National Resilience was positioned to meet the increasing demand for biopharmaceutical manufacturing, especially in the wake of global health crises.

In 2009, Baxter International Inc. was a prominent healthcare company involved in vaccine development and manufacturing. Here's an overview of its board composition during that time, subsequent developments, and its relationship with Nanotherapeutics (later Ology Bioservices):

Baxter's Board of Directors in 2009

Complete Board is unavailable to cite, but these are a few key executives that held significant roles during this period:

- **John Greisch**: Served as Director of Finance/CFO from December 2003 to December 2005 and continued as a Corporate Officer/Principal until April 2009. (MarketScreener UK)
- **Norbert Riedel**: Held the position of Chief Technology/Science/R&D Officer from December 1997 to December 2012. (MarketScreener UK)
- **Joy Amundson**: Acted as a Corporate Officer/Principal from July 2004 to October 2010. (MarketScreener UK)
- **Bruce H. McGillivray**: Functioned as a Corporate Officer/Principal from December 2001 to July 2010. (MarketScreener UK)
- **Thomas Sabatino**: Served as General Counsel from December 1994 to October 2009. (MarketScreener UK)

Baxter's Developments Post-2009

In the years following 2009, Baxter underwent several significant changes:

- **Divestiture of Vero Cell Vaccine Platform**: In December 2014, Baxter sold its proprietary Vero cell-based vaccine manufacturing platform to Nanotherapeutics, Inc. This technology was pivotal for producing vaccines using cell culture methods. (Fierce Pharma)
- **Corporate Restructuring**: Baxter's BioScience division was spun off to form Baxalta in 2015, which was later acquired by Shire and subsequently became part of Takeda Pharmaceutical Company.(Takeda Pharmaceuticals: Global Homepage)

Relationship with Nanotherapeutics/Ology Bioservices

The relationship between Baxter and Nanotherapeutics evolved over time:

- **Acquisition of Vero Cell Technology**: As mentioned, Nanotherapeutics acquired Baxter's Vero cell-based vaccine platform in 2014, enhancing its capabilities in vaccine development.
- **Rebranding to Ology Bioservices**: In 2017, Nanotherapeutics rebranded as Ology Bioservices to reflect its transformation into a leading contract development and manufacturing organization (CDMO) specializing in vaccines and biologics. (Press Release Services)
- **Partnership with Takeda**: In 2015, Takeda Pharmaceutical Company entered into an agreement with Nanotherapeutics (now Ology Bioservices) to expand commercialization and technology access rights related to the Vero cell technology platform, supporting influenza and other vaccine programs. (Takeda Pharmaceuticals: Global Homepage)

This series of transactions and partnerships underscores the strategic importance of the Vero cell technology in vaccine development and the collaborative efforts among these

companies to advance public health initiatives. Baxter International Inc. played a notable role in vaccine development leading up to and during the 2009 H1N1 pandemic.

🧬 Baxter's Vaccine Activities and Divestment

In the early 2000s, Baxter was actively involved in developing cell-based vaccines using its proprietary Vero cell technology. This platform was utilized to produce vaccines for various influenza strains, including H5N1 and H1N1.(GEN)

However, by 2014, Baxter decided to exit the vaccine market. In December of that year, the company sold its Vero cell technology and related assets—including a manufacturing facility in Bohumil, Czech Republic—to Nanotherapeutics, a biopharmaceutical company based in Florida. This sale included developed vaccines for H5N1, H1N1, and seasonal influenza, as well as investigational vaccine programs for Ross River virus, Chikungunya virus, and West Nile virus .(Fierce Pharma, GEN)

The divestiture was part of Baxter's strategy to focus on its core therapeutic areas of hematology, oncology, and immunology, especially as it prepared to spin off its biopharmaceutical division into a separate entity, Baxalta, in 2015.(Fierce Pharma)

👥 Baxter's Board of Directors in 2009

While a complete list of Baxter's board members in 2009 isn't readily available, it's known that Albert P.L. Stroucken served on the board starting in 2004 . Stroucken brought extensive experience from his leadership roles in companies like H.B. Fuller and Owens-Illinois. Other board members during that period would have included senior executives and industry leaders, but specific details would require access to Baxter's 2009 annual report or proxy statements.(Wikipedia)

🤝 Relationship with Nanotherapeutics/Ology Bioservices

Nanotherapeutics, founded in 2000, initially focused on nanometer-scale particle technology for drug delivery. By 2013, the company had shifted its focus to become a biologics contract development and manufacturing organization (CDMO), specializing in the production of vaccines and other biologics.(Wikipedia)

In 2014, Nanotherapeutics acquired Baxter's Vero cell technology and the associated Czech manufacturing facility. This acquisition significantly enhanced Nanotherapeutics' capabilities in vaccine production. In 2017, the company rebranded as Ology Bioservices to reflect its broader focus on biologics manufacturing .(GEN, Wikipedia)

Ology Bioservices has since become a key player in the biopharmaceutical manufacturing sector, providing services to both government and commercial clients. The acquisition of Baxter's assets played a crucial role in this transformation.

📌 Summary

- **Baxter's Role in H1N1**: Developed cell-based vaccines using Vero cell technology.
- **Divestment**: Sold Vero cell platform and related assets to Nanotherapeutics in 2014.
- **Board Leadership**: Included Albert P.L. Stroucken among others in 2009.
- **Nanotherapeutics/Ology Transition**: Acquired Baxter's vaccine assets, rebranded as Ology Bioservices in 2017, and expanded biologics manufacturing services.(Pulmonx, GEN, Wikipedia, Wikipedia)

Key Points:

1. **Contamination Incident in Early 2009 (Pre-H1N1 Pandemic):**

- **In early 2009**, Baxter accidentally shipped **contaminated flu vaccine materials** from its Austrian facility to several European countries.
- The material was intended for seasonal flu vaccine research and was found to be **contaminated with live H5N1 (avian flu virus)**.
- The shipment went to a subcontractor in the Czech Republic, who tested it on ferrets — and they died, which raised alarm.
- The incident did **not** result in any reported human infections or deaths.
- It led to investigations and concern about **biosafety protocol breaches**, particularly given how dangerous H5N1 is when combined with seasonal flu strains.

2. **Baxter's Role During the H1N1 Pandemic (Mid–Late 2009):**

- Baxter was one of several pharmaceutical companies contracted to **develop and manufacture H1N1 (swine flu) vaccines** during the pandemic.
- The company developed a **cell-based vaccine** for H1N1, which was seen as a more modern and potentially faster alternative to traditional egg-based methods.

Conclusion:

- **Baxter did not cause the H1N1 pandemic**, but the company was embroiled in a separate, serious **lab safety incident** earlier in 2009 involving a different flu strain (H5N1).
- The timing of the contamination event and the pandemic fueled various conspiracy theories, but there is **no credible evidence** linking Baxter to the origin or spread of H1N1.

OLOGY

Between 2018 and 2019, Ology Bioservices secured several significant contracts with the U.S. Government, primarily through the Department of Defense (DoD) and the National Institutes of Health (NIH). Below is a chronological overview of these agreements:

August 2018: $8.4 Million DoD Contract for Anti-Ebola Monoclonal Antibody Production

Ology Bioservices was awarded an Other Transaction Agreement (OTA) by the Joint Project Manager Medical Countermeasure Systems (JPM-MCS), a component of the Joint Program

Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND). The contract, valued at $8.4 million, was to manufacture an anti-Ebola monoclonal antibody (mAb114), developed by the NIH's Vaccine Research Center. The project involved technology transfer and cGMP manufacturing at Ology's facility in Alachua, Florida. (BioSpace, Contract Pharma)

April 2019: Two DoD Contracts Totaling $135.4 Million

In April 2019, Ology Bioservices received two contracts from the DoD's Platforms for Rapid Integrated Solutions for Medical Countermeasures (PRISM) office:(Pharmaceutical Outsourcing)

1. **$130.3 Million Contract for Monoclonal Antibody Platform Development**
2. This 10-year contract focused on developing a monoclonal antibody platform prototype as medical countermeasures against threats like Yersinia pestis, the bacterium causing plague. The program aimed to explore the use of monoclonal antibodies as next-generation medical countermeasures against chemical and biological threats.
3. **$5.1 Million Contract for Plasmid DNA Manufacturing Technology**
4. This 30-month contract aimed to develop a prototype manufacturing platform for cGMP production of plasmid DNA, which is crucial for DNA vaccines and gene therapy. The project sought to enhance rapid and efficient delivery of biodefense medical countermeasures.

August 2019: NIH Contract for Biodefense Research

Ology Bioservices was awarded a definitive contract (Contract No. 75N93019C00057) by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH. The contract, valued at up to $26.4 million over five years, was to support research and development in biodefense. As of the award date, $15.2 million had been obligated. These contracts reflect Ology Bioservices' significant role in advancing biodefense initiatives through the development and manufacturing of critical medical countermeasures.(Press Release Services)

Between 2018 and 2019, Ology Bioservices, Inc. secured several significant contracts with the U.S. government, particularly focusing on medical countermeasures and advanced biologics manufacturing. Here's a detailed overview:(BioSpace)

2018

$8.4 Million DoD Contract for Anti-Ebola Monoclonal Antibody Production

- **Awarding Agency**: Joint Project Manager Medical Countermeasure Systems (JPM-MCS), under the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)
- **Contract Type**: Other Transaction Agreement (OTA)

- **Purpose**: Manufacture the anti-Ebola monoclonal antibody mAb114, developed by the NIH's Vaccine Research Center.
- **Scope**: Technology transfer and cGMP manufacturing at Ology's 183,000 sq ft facility in Alachua, FL.
- **Timeline**: Initial 500L batch delivery by December 2018, with options for two additional lots in early 2019. (BioSpace)

2019

$130.3 Million DoD Contract for Monoclonal Antibody Platform Development

- **Awarding Agency**: Department of Defense's Platforms for Rapid Integrated Solutions for Medical Countermeasures (PRISM) office
- **Duration**: 10 years
- **Purpose**: Develop a monoclonal antibody platform prototype targeting Yersinia pestis (plague) as part of the ADAMANT initiative.
- **Collaborators**: Duke Human Vaccine Institute, Just Biotherapeutics, Mapp Biopharmaceutical, USAMRIID, Cato Research, Certara, and Battelle. (Press Release Services, Pharmaceutical Outsourcing)

$5.1 Million DoD Contract for Plasmid DNA Manufacturing Platform

- **Awarding Agency**: PRISM office
- **Duration**: 30 months
- **Purpose**: Develop a prototype manufacturing platform for cGMP production of plasmid DNA, supporting genetic vaccines and gene therapies. (Press Release Services, GovCon Wire)

$26.4 Million NIH/NIAID Contract for Biologics Development

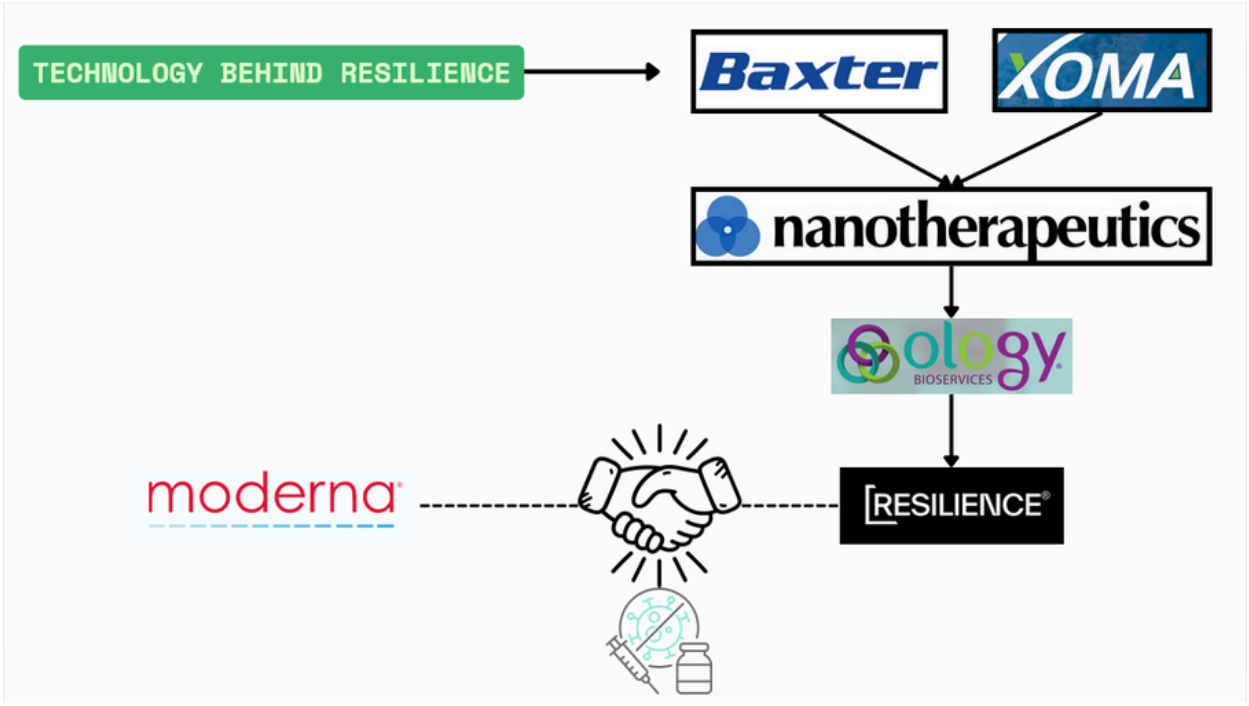
- **Awarding Agency**: National Institute of Allergy and Infectious Diseases (NIAID)
- **Contract Number**: 75N93019C00057
- **Award Date**: August 30, 2019
- **Purpose**: Support biologics development under the HHS-NIH-NIAID-BAA2018 initiative.
- **Obligations to Date**: $15.2 million
- **Duration**: 5 years, concluding on August 17, 2024.

These contracts underscore Ology Bioservices' pivotal role in advancing the U.S. government's capabilities in biodefense and pandemic preparedness during this period.

The designation **HHS-NIH-NIAID-BAA2018** refers to the **2018 Omnibus Broad Agency Announcement (BAA)** issued by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). This BAA served as a formal solicitation inviting proposals for research and development in areas critical to national health security, including:

- Advanced development of vaccine candidates for biodefense and emerging infectious diseases

- Development of therapeutic products
- Innovative technologies for infectious disease research
- Strategies to combat antimicrobial resistance(Federal Register)

The BAA was first issued on **June 1, 2018**, with subsequent amendments to address specific research areas and provide clarifications to potential offerors. It was accessible electronically through platforms like FedBizOpps.gov (now beta.SAM.gov) .(Grants.gov)

Under this announcement, various contracts were awarded to organizations capable of advancing NIAID's mission. For instance, on **August 30, 2019**, Ology Bioservices received a contract under this BAA to support the development of medical countermeasures, reflecting the BAA's role in facilitating partnerships between the NIH and external entities to address pressing public health challenges.